REMARKS

Applicants respectfully request reconsideration of the present case in view of the above amendments and the following remarks.

Claims 18-22 are currently pending. Claims 18-20 and 22 have been amended. No new matter has been inserted. Claims 18-20 and 22 were simply amended for purposes of clarification.

Claims 19 and 20 were objected to as the Examiner stated it is unclear why the claims refer to both the HCV polyprotein and parenthetically to the HCV core antigen. Claims 19 and 20 have been amended in order to render this objection moot. Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. § 112

Claims 18-22 were rejected under 35 U.S.C. § 112, second paragraph as indefinite. Applicants respectfully traverse this rejection.

Specifically, the Examiner stated that is unclear what is meant by "and/or". While not conceding the correctness of the Examiner's position, in the interest of advancing prosecution, Applicants have amended claim 18 to eliminate this term. Applicants respectfully request that this rejection be withdrawn.

The Examiner further stated that claim 22 was unclear what the phrase "with 12 to 16 carbon atoms" was describing. In response, Applicants have amended claim 22 in order to obviate this rejection. Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. § 103

Claim 18 was rejected under 35 U.S.C. 103(a) as unpatentable over Masalova et al., *J. Med. Virol*, in view of Papatheodoridis et al., *J. Hepatol*, and further in view of Ling et al., GB 2,051,357, and Schönbrunner, GB 2,313,666. The Examiner alleges that it would be obvious to

apply the double antibody/antigen detection methods applied in the Ling and Schönbrunner references to the detection and diagnosis of HCV. Applicants respectfully traverse this rejection.

As conceded by the Examiner, Masalova and Papatheodoridis both fail to teach or suggest the simultaneous detection of both HCV core antigen and antibodies thereto in the same vessel, as required by claim 18. Ling and Schönbrunner fail to cure the deficiencies of Masalova and Papatheodoridis.

The Examiner alleges that the abstract of Ling suggests that the peptide used to detect antibodies in the sample lack the epitope recognized by the antibody since Ling discloses that the two different immunoreactants are "non-complementary". In response, Applicants point out that when Ling discloses a "non-complementary" antigen and antibody for use in the assay, it is referring to HBc antigen and antibodies to BHs antigen. See, e.g., p. 2, lines 14-23. Accordingly, Ling does not disclose or suggest antibodies for the detection of HCV core antigen and at least one peptide for the detection of HCV core antibodies, as required by the invention of claim 18.

The Examiner further alleges that Schönbrunner, on pages 7-8, indicates that multiple epitopes may be present on any particular antigen and that this indicates that the peptide and antibody used to detect antigen and antibody in the sample may both target different epitopes in the same protein. In response, Applicants point out that Schönbrunner does not disclose or suggest antibodies for the detection of an antigen and at least one peptide for the detection of antibodies to the antigen, at the same time and in the same vessel, as required by the invention of claim 18. Accordingly, Schönbrunner does not disclose or suggest the invention of claim 18.

Therefore, the combination of Masalova, Papatheodoridis, Ling, and Schönbrunner fails to teach or suggest the invention of claim 18. Applicants respectfully request that this rejection be withdrawn.

Claim 18 was rejected under 35 U.S.C. 103(a) as being unpatentable over Simmonds et al., WO 93/10239, in view of Ling and Schönbrunner. Applicants respectfully traverse this rejection.

Simmonds discloses assays for the diagnosis of HCV infections. However, as conceded by the Examiner, Simmonds does not disclose an assay for detecting both HCV core protein

antigens and antibodies in a sample. Ling and Schönbrunner fail to cure the deficiencies of Simmonds.

As discussed above, Ling discloses using HBc antigen and antibodies to BHs antigen. This is in sharp contrast to the present invention of claim 18 wherein a HCV core antigen and antibodies for the detection of HCV core antigen are assayed for in the same reaction vessel. Further, Schönbrunner does not disclose or suggest antibodies for the detection of an antigen and at least one peptide for the detection of antibodies to the antigen, at the same time and in the same vessel, as required by the invention of claim 18. Therefore, the combination of Simmonds with Ling and Schönbrunner fails to suggest the invention of claim 18. Applicants respectfully request that this rejection be withdrawn.

Claims 19-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Masalova and Papatheodoridis, or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further in view of either Lacroix (EP 0507615) or Seidel et al., US 6,183,949. Applicants respectfully traverse this rejection.

As conceded by the Examiner, Masalova, Papatheodoridis, and Simmonds, fail to teach or suggest the simultaneous detection of both HCV core antigen and antibodies thereto in the same vessel, as required by claim 18. As discussed above, Ling and Schönbrunner fail to cure the deficiencies of Masalova, Papatheodoridis, and Simmonds. Specifically, Ling discloses using HBc antigen and antibodies to BHs antigen in sharp contrast to the present invention of claim 18 wherein a HCV core antigen and antibodies for the detection of HCV core antigen are assayed for in the same reaction vessel. Similarly, Schönbrunner does not disclose or suggest antibodies for the detection of an antigen and at least one peptide for the detection of antibodies to the antigen, at the same time and in the same vessel, as required by the invention of claim 18. Lacroix and Seidel fail to cure the deficiencies of Masalova, Papatheodoridis, Simmonds, Ling, and Schönbrunner.

Lacroix discloses peptides useful for detecting and quantifying HCV infections. However, Lacroix fails to teach or suggest the simultaneous detection of both HCV core antigen and antibodies thereto in the same vessel, as required by claim 18. Seidel discloses HCV peptide antigens and methods for the determination of HCV. However, Lacroix fails to teach or suggest

the simultaneous detection of both HCV core antigen and antibodies thereto in the same vessel, as required by claim 18.

Therefore the combination of Masalova and Papatheodoridis, or of Simmonds, in view of Ling and Schönbrunner, and further in view of either Lacroix or Seidel fails to teach or suggest the invention of claim 18. As claims 19 and 20 are dependent on claim 18, they are also not obvious. Applicants respectfully request that this rejection be withdrawn.

Claims 21-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Masalova and Papatheodoridis or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and furthering view of either of Cheng et al., US 5,627,080, or Khanna et al., US 5,032,503. Applicants respectfully traverse this rejection.

As conceded by the Examiner, Masalova, Papatheodoridis, and Simmonds, fail to teach or suggest the simultaneous detection of both HCV core antigen and antibodies thereto in the same vessel, as required by claim 18. As discussed above, Ling and Schönbrunner fail to cure the deficiencies of Masalova, Papatheodoridis, and Simmonds. Specifically, Ling discloses using HBc antigen and antibodies to BHs antigen in sharp contrast to the present invention of claim 18 wherein a HCV core antigen and antibodies for the detection of HCV core antigen are assayed for in the same reaction vessel. Similarly, Schönbrunner does not disclose or suggest antibodies for the detection of an antigen and at least one peptide for the detection of antibodies to the antigen, at the same time and in the same vessel, as required by the invention of claim 18. Cheng and Khanna fail to cure the deficiencies of Masalova, Papatheodoridis, Simmonds, Ling, and Schönbrunner.

Cheng discloses the use of detergents to achieve a desired assay sensitivity of immunoassays. However, the description of Cheng fails to suggest a detergent suitable specifically for an HCV core assay. Further, Cheng fails to teach or suggest the simultaneous detection of both HCV core antigen and antibodies thereto in the same vessel, as required by claim 18. Khanna discloses immunoassay reagents for competitive inhibition assays. However, Khanna fails to teach or suggest the simultaneous detection of both HCV core antigen and antibodies thereto in the same vessel, as required by claim 18.

Therefore the combination of Masalova and Papatheodoridis, or of Simmonds, in view of Ling and Schönbrunner, and further in view of either Cheng or Khanna fails to teach or suggest

the invention of claim 18. As claims 21 and 22 are dependent on claim 18, they are also not obvious. Applicants respectfully request that this rejection be withdrawn.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Dated: January 27, 2005

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